

## REMARKS/ARGUMENTS

The final action has been carefully considered. Before entry of this paper, the status of the application is as follows:

- Claims 10-15, 19-22, 25, and 26 are pending in the application.
- Claims 10, 19, 21, 25, and 26 are rejected under 35 U.S.C. § 102(e) over Devonec et al. (U.S. Pat. No. 5,876,417).
- Claims 11-15, 20, and 22 are rejected under 35 U.S.C. § 103(a) over Devonec et al. (U.S. Pat. No. 5,876,417) in view of Rovegno et al. (GB No. 2348148).

In view of the following remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 10-15, 19-22, 25, and 26.

1. Applicants thank the Examiner for participating in a telephone interview with Applicants' representatives, Robert J. Tosti and Brian M. Gaff, held on 7-Sep-05. The rejections, and particularly Devonec et al. (U.S. Pat. No. 5,876,417), were discussed. Agreement on allowable claims was not reached. This Response is consistent with the points discussed in the interview.
2. Applicants traverse the rejection of claims 10, 19, 21, 25, and 26 under 35 U.S.C. § 102(e) over Devonec et al. (U.S. Pat. No. 5,876,417). Applicants respectfully traverse this rejection.

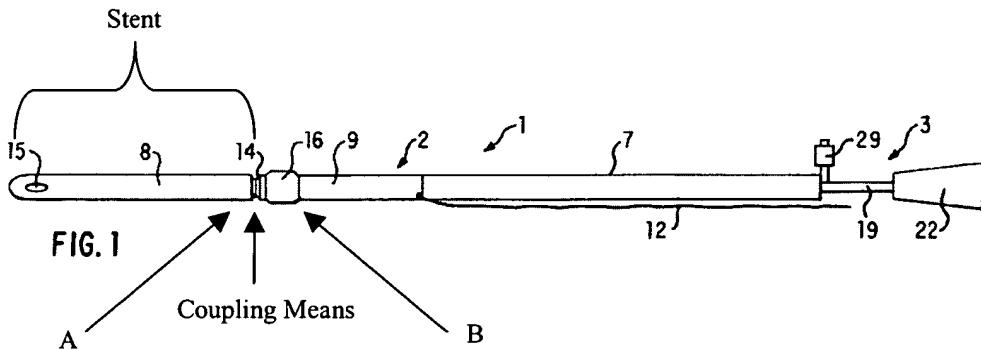
Each of the independent claims 10, 19, and 25 recite, in part, a prostatic stent-catheter system comprising (i) a stent comprising a body member that includes a distal terminating end, and (ii) a connecting segment comprising an elongated body member that includes a proximal end releasably joined to the distal terminating end by a member that is fastened to the proximal end and slip fit into the distal terminating end.

The final action indicates that only the upper tubular element 8 of Devonec et al. corresponds to Applicants' claimed stent, and that Devonec et al. discloses a catheter with "a connecting segment 7 releasably joined to the distal end of the [upper] tubular element 8 via coupling means 14," with the coupling means 14<sup>1</sup> "inherently joined by slip fitting" into the stent

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<sup>1</sup> Referred to as the "connection means 14" in Devonec et al.; *see, e.g.*, col. 4, l. 16.

because Figure 7 of Devonec et al. shows that the “coupling member 14” has a smaller diameter than that of the stent. Final action, p. 2. The annotated excerpt of Figure 1 of Devonec et al., below, illustrates this interpretation:



Applicants respectfully disagree with this characterization of Devonec et al. Even assuming, *arguendo*, that Applicants’ claimed distal terminating end and proximal end correspond to points or sections “A” and “B,” respectively, in the excerpted Figure 1 above (which Applicants do not concede or agree with), Devonec et al. still would fail to teach or suggest a member fastened to “B” and slip fit into “A.” Devonec et al. lacks any disclosure at all about a slip fit. (Applicants note that “[i]nherency ... may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *In re Olerich*, 666 F.2d 578, 581, 212 U.S.P.Q. (BNA) 323, 326 (C.C.P.A. 1981) (quoting *Hansgirg v. Kemer*, 102 F.2d 212, 214, 40 U.S.P.Q. (BNA) 665, 667 (C.C.P.A. 1939))).

Also, Devonec et al. fails to disclose that the “connecting segment 7<sup>2</sup>” is releasably joined to the distal end of the tubular element 8 via coupling means 14. In Devonec et al., connection means 14 always remains connected to upper tubular element 8. As shown in Figure 7 of Devonec et al., the connection means 14 traverses the (external) sphincter 13 to give the patient self control over the flow of liquid out of the body. Specifically:

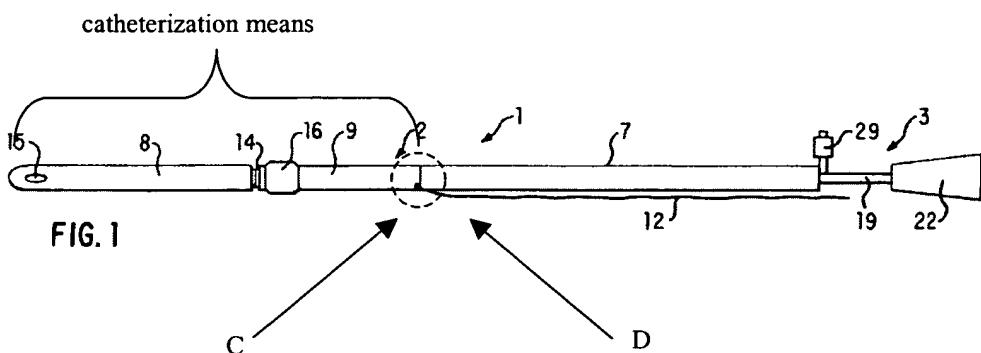
[t]he upper and lower tubular elements 8 and 9 are connected to one another via a flexible and deformable connection means 14 which is intended to be placed in the orifice 13a of the sphincter 13. The connection means 14 permits the normal play of the striated muscular sphincter 13 and ensures the flow of the liquid between the upper and lower tubular elements 8, 9.

Col. 4, ll. 14-20. Elements 8 and 9 clearly are described as being connected to each other via the means 14. Any disconnection of the upper tubular element 8 from the connection means

<sup>2</sup> Referred to as the “pusher tube 7” in Devonec et al.; *see, e.g.*, col. 4, ll. 46-47.

14 might be a problem because Devonec et al. describes no way to extract the element 8 other than by forceps or a filament 12 that is connected to the element 9. Col. 7, ll. 49-53.

In contrast to the characterization of Devonec et al. that is provided in the final action, Applicants respectfully submit that Devonec et al. discloses a catheterization means 2 having upper and lower tubular elements 8, 9 and an introduction means 3 that includes a pusher rod 7. Col. 3, ll. 58-67. The pusher rod 7 is either aligned or coaxial with the catheterization means 2. *Id.* In the embodiment where the pusher rod 7 is aligned with the catheterization means 2, these elements abut at the location circled in the annotated excerpt of Figure 1 of Devonec et al. below.



Even assuming, *arguendo*, that Applicants' claimed distal terminating end and proximal end correspond to points or sections "C" and "D," respectively, in the excerpted Figure 1 directly above, Devonec et al. still would fail to teach or suggest a member fastened to "D" and slip fit into "C." Devonec et al. merely discloses that the introduction means 3 is disconnected from the catheterization means 2 (see, e.g., col. 3, ll. 65-67), but Devonec et al. does not teach or suggest anything about the fastening or slip fitting recited in each of Applicants' independent claims.

The structural distinctions between Applicants' claims and the disclosure in Devonec et al. should now be clear. The unique structure allows operation that is not taught or suggested anywhere in Devonec et al. As described in Applicants' Specification (see, e.g., paragraph [0008] of the published application, U.S. Pub. No. 2002/0072788), Applicants' device can either drain the patient's bladder continuously (i.e., operate as a Foley catheter) or be modified in situ to allow the patient's external sphincter full control over voiding of urine (i.e., operate as a prostatic stent). This is accomplished by a connecting segment that is releasably joined to a stent using a member, as recited in the claims.

In view of the above, Applicants respectfully submit that independent claims 10, 19, and 25 are patentable over Devonec et al. Because claims 21 and 26 depend from claims 10 and 25, respectively, Applicants submit that these claims are allowable as well. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 10, 19, 21, 25, and 26 under 35 U.S.C. § 102(e) over Devonec et al.

3. Applicants also traverse the rejection of claims 11-15, 20, and 22 under 35 U.S.C. § 103(a) over Devonec et al. (U.S. Pat. No. 5,876,417) in view of Rovegno et al. (GB No. 2348148).

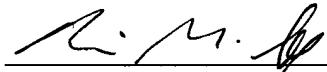
Claims 11-15, 20, and 22 depend directly or indirectly from independent claim 10. Rovegno et al. does not address or cure any of the deficiencies of Devonec et al. with respect to at least the member recited in part “(c)” of claim 10. Claim 10 is, therefore, patentable over Devonec et al. and Rovegno et al., whether taken alone or in some combination. Because claims 11-15, 20, and 22 depend directly or indirectly from claim 10, these dependent claims are allowable as well. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 11-15, 20, and 22 under 35 U.S.C. § 103(a) over Devonec et al. in view of Rovegno et al.

## CONCLUSION

In view of the foregoing, Applicants submit that claims 10-15, 19-22, 25, and 26 are allowable. Applicants respectfully request entry of this Response, reconsideration, and early favorable action by the Examiner.

The Examiner is cordially invited to contact Applicants' undersigned representative at the number listed below to discuss any outstanding issues.

Respectfully submitted,



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